

KIRKLAND & ELLIS LLP

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February 27, 2025

VIA ECF

The Honorable Thomas I. Vanaskie
Special Master for Discovery
Stevens & Lee
1818 Market Street, 29th Floor
Philadelphia, PA 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No.
1:19-md-2875-RBK-KMW (D.N.J.)

Dear Special Master Vanaskie:

Per the Court's MDL Special Master Order (ECF 2969), this letter provides Defendants' proposed agenda for the March 3, 2025 Case Management Conference.

I. PLAINTIFF FACT SHEET DEFICIENCIES

Cases Addressed at the February 1, 2024 Case Management Conference:

Plaintiff Fact Sheet Deficiencies and Orders to Show Cause were last an agenda item at the February 1, 2024 Case Management Conference ("CMC"). Following that CMC, the Court issued one show cause order returnable at the next Case Management Conference:

1. *E/O Alexandra Samocha v. Hetero, et al.* – 21-cv-17384

The issues in the *Samocha* matter are resolved and the order to show cause may be withdrawn.

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Second Listing Cases – Order to Show Cause Requested:

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these cases was previously listed on the agenda for a prior CMC. This list was provided to Plaintiffs' leadership on February 14, 2025, and a meet and confer was held on February 25, 2025. Defendants have also been available for further discussion as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why these cases should not be dismissed.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Jerry Anderson v. Aurobindo Pharma, Ltd., et al.	23-cv- 13680	Farr, Farr, Emerich, Hackett, Carr & Holmes P.A.	Missing proper estate representation documentation for all causes of action besides wrongful death.	12/19/23

First Listing Cases – Remaining Core Deficiencies:

The following Plaintiff Fact Sheets contain core deficiencies which remain unresolved. This list was provided to Plaintiffs' leadership on February 14, 2025, and a meet and confer was held on February 25, 2025. Defendants have also been available for further discussion as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not

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requesting orders to show cause with respect to any of the below cases at this time and will
continue to meet and confer to resolve these deficiencies.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Bobby Williams v. Zhejiang Huahai Pharmaceutical Co., Ltd et al	1:23-cv- 22452	Levin Papantonio	Missing information on 2023 income (making a lost wage claim for time in 2023).	2/20/24
2.	Mark McNall v. Aurobindo, et al.	23-cv- 21327	Fleming Nolen	Missing medical expense records for Palm Bay Physical Therapy. Missing , mental health authorizations for Condo & Ungredda. Missing & HIPAA authorization for Regalado regarding emotional injury claim, insurance authorization for WFS Health Insurance, workers comp. authorization.	2/21/24
3.	Edron Harris v. Doe	24-cv-546	Parafinczuk Wolf	Prescription #2 is entirely outside of recall date. Authorizations must be undated. No PID as to any Defendant. Only John Doe named in complaint.	3/22/24

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
4.	Soraya Svoronos v. Torrent, et al.	23-cv- 22220	Dell and Dean PLLC	No authorizations. Dietary questions blanks.	3/22/24
5.	Joseph Tinsley v. CVS, et al.	24-cv- 2659	Parafinczuk Wolf	Authorizations must be undated. Only John Doe manufacturers named in complaint.	4/23/24
6.	Harry Wicks v. ZHP, et al.	24-cv- 6188	Nigh Goldenberg	PFS substantially incomplete. No records, no authorizations.	8/12/24
7.	Kurt Wiseth v. ZHP, et al.	24-cv- 6211	Nigh Goldenberg	PFS substantially incomplete. No records, no authorizations.	8/12/24
8.	Kursat Saatci v. ZHP, et al.	24-cv- 7708	Nigh Goldenberg	PFS substantially incomplete. No records, no authorizations.	10/16/24
9.	Jeannette Stern v. ZHP, et al.	24-cv- 9402	Bernstein Liebhard LLP	Need billing records. Need health insurance authorization. All authorizations must be undated.	1/20/25

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
10.	Melinda Parker v. Solco Healthcare U.S., LLC, et al	24-cv- 05199	Honik LLC	Failed to provide medical expenses.	7/15/24
11.	Christakis Nicolaou v. Aurobindo Pharma, Ltd., et al.	1:24-cv- 4506	Nigh Goldenberg	PFS is substantially incomplete. Failure to attach any medical or prescription records. Failure to upload health care and insurance authorizations.	6/20/24
12.	Lionel Robertson v. Aurobindo Pharma, Ltd., et al.	1:24-cv- 06207	Nigh Goldenberg	Failure to attach any medical or prescription records. Failure to upload health care and insurance authorizations. Failure to provide signed and dated declaration.	8/5/24

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
13.	Shirley Thomas v. Aurobindo Pharma, Ltd., et al.	1:23-cv-01700	Terrell Hogan	<p>Failure to attach any medical or prescription records.</p> <p>Failure to upload health care and insurance authorizations.</p> <p>Failure to provide signed and dated declaration.</p> <p>Included NDC code for non-recalled AB losartan.</p> <p>Discrepancies with SFC in terms of Defendants.</p>	8/14/24
14.	Thomas Love v. Aurobindo, et al.	1:24-cv-07106	Morgan & Morgan	<p>No subject matter jurisdiction and awaiting voluntary dismissal of non-diverse defendants.</p> <p>Amended PFS still lists non-diverse defendants and claims damages from non-diverse defendants' products.</p>	9/10/24
15.	Robert Jaskulski	24-cv-5752	Nigh Goldenberg	<p>No authorizations.</p> <p>No medical records or pharmacy records</p>	9/10/24

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
16.	Lisa Hill	24-cv-9171	Levin Papantonio	No billing records.	11/27/24
17.	Asad Farhad	1:24-cv-10220	Nigh Goldenberg	Insurance authorizations are missing SSN.	1/8/25
18.	E/O Betty Baker v. Teva, et al.	20-cv-17108	Watts Guerra	No PFS Filed	PFS Due – 1/24/21
19.	Teresa Esrig v. Torrent, et al.	22-cv-244	Rios Law Firm	No PFS Filed	PFS Due – 2/29/22
20.	Christopher Hurst v. Teva, et al.	23-cv-20308	Pro Se	No PFS Filed	PFS Due – 2/7/24
21.	George Stokes v. ZHP, et al.	21-cv-20419	Powell & Swanick	No PFS Filed	PFS Due – 1/18/22
22.	Yolanda Williams v. Hetero, et al.	23-cv-13792	Cronauer Law, LLP	No PFS Filed	PFS Due – 4/7/24

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
23.	Candece Morgan v. Aurobindo Pharma, Ltd. et al	24-cv-08894	Chaffin Luhana	No PFS Filed	PFS Due - 10/29/24
24.	Darren Daniels v. Mylan Laboratories Ltd. et al	24-cv-09469	Morgan & Morgan	No PFS Filed	PFS Due - 11/25/24

II. PRODUCT IDENTIFICATION DEFICIENCIES

Pursuant to the Court’s instructions at the January 31, 2025 Case Management Conference and as ordered in ECF No. 2969, on February 25, 2025, the parties met and conferred to discuss a proposed process for addressing dismissal of individual cases for lack of product identification information (“PID”). Ahead of that meet and confer, Defendants shared the draft text of the attached proposed order with Plaintiffs’ counsel (*see* Exhibit 1), and believe the parties are in general agreement as to the process. Defendants believe this process can and should commence ahead of the next scheduled CMC with a first listing of cases with PID deficiencies, which will allow Plaintiffs a minimum of approximately three months to cure any PID deficiencies before being subject to dismissal.

To the extent there are minor disagreements over specific dates or provisions for implementing the process, Defendants will continue to meet and confer with Plaintiffs’ counsel

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and will be prepared to address any outstanding disputes with the Court at the March 3 CMC with the goal of submitting a proposed agreed order for entry by the Court shortly thereafter.

III. PARTIES' FEBRUARY 14, 2025 LETTERS TO COURT RE WAVE 2 TRIAL PROPOSAL

As the Court is aware, the parties submitted letters on February 14, 2025 setting forth their positions regarding the Wave 2 bellwether trial proposal. (ECF Nos. 2972, 2973.) Defendants will be prepared to address their positions as set forth in those letters at the Case Management Conference.

IV. STATUS OF EFFORTS TO REACH A STIPULATION ON ZHP CERTIFICATES OF ANALYSIS AND MATERIAL SAFETY DATA SHEETS

ZHP has been working cooperatively with Plaintiffs with respect to a proposed stipulation to address Plaintiffs' request for certificates of analysis ("COAs") and material safety data sheets ("MSDSs") applicable to the dimethylformamide ("DMF") solvent and triethylamine ("TEA") used in connection with the manufacture of valsartan, losartan, and irbesartan API.

The stipulation was intended to avoid the need for ZHP to expend significant time and resources producing the large number of COAs and MSDSs in its possession, which exist only in hard copy. ZHP proposed an initial version of that stipulation in January 2025, along with producing a representative sample of the COAs and MSDSs at issue. The initial stipulation proposed by ZHP set forth the content of the produced COAs and MSDSs and stipulated that the additional COAs and MSDSs that ZHP received would include the same substantive content.

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The parties were in large part able to reach agreement regarding the stipulation as it applied to the COAs and MSDSs applicable to the TEA ZHP received, as well as the MSDSs for DMF solvent. Throughout the negotiation process, however, the parties were in disagreement about the stipulation as it applied to the COAs for the DMF solvent. Plaintiffs took the position that ZHP was required to not only stipulate to the content of the COAs it received, but also agree to Plaintiffs' interpretation of the meaning of those documents, including that the documents stated or could be interpreted to state that dimethylamine ("DMA") was present as an impurity in the DMF solvent ZHP received. ZHP repeatedly made clear that it disagreed with Plaintiffs' interpretation and could not agree to a stipulation suggesting that the company believed that the COAs for DMF referenced DMA as an impurity. Nevertheless, ZHP worked in good faith to attempt to find language that might be agreeable to both parties.

ZHP submitted its most recent proposed version of the stipulation to Plaintiffs on February 24, 2025. Earlier today, Plaintiffs told ZHP that they intended to inform the Court that negotiations are at an impasse, that Plaintiffs will seek sanctions against ZHP related to its alleged failure to produce relevant COAs and MSDSs, and that they would be asking the Court to set a briefing schedule with respect to a sanctions motion. ZHP disagrees with Plaintiffs that a motion for sanctions based on an alleged failure to produce COAs and MSDSs is appropriate at this juncture. As ZHP has made clear to Plaintiffs, although the purpose of the stipulation was to avoid burdensome production of thousands of documents containing duplicative content, if the parties are unable to reach an agreement, ZHP can collect and produce the COAs and MSDS in

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its possession. ZHP has begun this process.¹ Thus, ZHP has not refused to produce the materials at issue, responsive documents are forthcoming, and Plaintiffs should evaluate that production before any briefing. As a result, any motion for sanctions based on the failure to produce COAs is premature.

If, however, the Court decides that a motion is appropriate at this time, ZHP asks that the Court set the due date for Plaintiffs' motion as March 14, allow ZHP until April 4 to file its opposition, and allow Plaintiffs until April 11 to submit a reply.

V. STATUS OF UPDATE TO ROBERTS DFS

The parties have been working cooperatively regarding Plaintiffs' requests for more information about the API used to manufacture Mr. Roberts' particular valsartan fills. In particular, because neither Mr. Roberts nor his pharmacy has additional label information or other records for the valsartan medication used to fill Mr. Roberts' prescriptions, the parties have been working together to narrow the potential finished dose lots from which Mr. Roberts' valsartan could have come. ZHP has amended its DFS response to list each of the potential finished dose lots from which Mr. Roberts' medication could have come, along with the corresponding API lot(s) used to make each finished dose lot. In the last few days, Plaintiffs have

¹ To the extent Plaintiffs' proposed motion for sanctions relates to DMF COAs issued prior to 2015, which were discarded by ZHP in the ordinary course of business, there is no evidence that these documents differ in any material way from the COAs and MSDSs ZHP is in the process of producing. While Plaintiffs identified a sample COA for DMF on the internet that includes different language, that COA refers to DMF sold in Japan and there is no evidence that language was used in COAs provided to Chinese manufacturers.

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asked ZHP to evaluate its calculations regarding the NDMA contained in each finished dose lot,
and ZHP is doing that.

VI. ISSUES RELATED TO JINSHENG LIN CUSTODIAL FILE

This morning, Plaintiffs sent a proposed stipulation regarding retention policies that
would have applied to Dr. Jinsheng Lin's emails and documents. ZHP is evaluating Plaintiffs'
proposal and will meet and confer with Plaintiffs regarding next steps.

Sincerely,

A handwritten signature in dark ink, appearing to read "Jessica Davidson".

Jessica Davidson, P.C.